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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,934	10/27/2003	Jacob Richter	2388/46607	2137

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,934	RICHTER ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/03,2/04,3/05,5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Israel on 14 May 1995. It is noted, however, that applicant has not filed a certified copy of the 113723 application as required by 35 U.S.C. 119(b).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 28 in Figures 9 and 10, and 133 in Figure 11. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words and 25 lines. Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because of the following informalities: Applicant omitted claim to Foreign Priority. Insert claim to Foreign Priority to the beginning of the disclosure. Appropriate correction is required.

5. The disclosure is objected to because of the following informalities: Sclera has been defined as element 12 on page 11 of the disclosure. Replace element "14" with --12-- on page 18, lines 2, 12, 13, and 15. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritch et al. (Patent No. 5,092,837).

Regarding claim 32, Ritch et al. disclose a method of implanting an intraocular

implant in an eyeball (column 3, lines 24-28) using a delivery device (Figure 4A, element 16) for implanting the intraocular implant (Figure 4B, element 21) into the eyeball (see Figures 3-4 for illustration). Figure 4D shows the intraocular implant (21) comprises a tube (since it is cylindrical and has a hollow passage) having an inlet end (portion inside the eyeball), an outlet end (portion on surface of the eyeball), and a tube passage (36) extending between the inlet end and the outlet end for permitting aqueous humor to flow out of the eyeball (column 6, lines 41-45). Figure 4C shows a flange (25) connected to the tube (21) at the outlet end of the tube for placing on a surface of the eyeball. Figure 4A shows a delivery device comprising a handle (38, 31,32), and a rod-like instrument (28) having a tip (35) for penetrating the tube passage (36) of the implant (21; see Figure 4B) and an abutment surface (29) for abutting the flange (25) of the implant (21).

Ritch et al. disclose attaching the implant (21) to the delivery device (16) with the tip (35) of the rod-like instrument (28) penetrating the tube passage (36) of the implant (column 5, lines 60-63), cutting an opening in a portion of the conjunctiva of the eyeball (column 4, lines 49-50; since the conjunctiva covers eyeball, it is inherent that the incision must be made through the conjunctiva portion) that lies at a distance away from an intended implantation site (opposite from the implantation site; see Figure 3), placing the implant (21) by the delivery device (16) through the opening in the conjunctiva (column 4, lines 55-57), directing the implant (21) by the delivery device (16) to the implantation site (column 4, line 57), inserting the implant (21) through the sclera

(18) at the implantation site (column 6, lines 6-31), and withdrawing the delivery device (column 6, lines 37-40).

Regarding claim 33, Figure 4B shows the abutment surface (29) of the delivery device (16) has an angle generally corresponding to an angle of the flange (25) of the intraocular implant (flange 25 is flat, or having an angle of 0 degrees, and abutment surface 29 is flat, or having a corresponding angle of 0 degrees).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Donowitz (Patent No. 3,788,327).

Regarding claim 34, Ritch et al. disclose a method of implanting an intraocular implant in an eyeball (column 3, lines 24-28) using a delivery device (Figure 4A, element 16) for implanting the intraocular implant (Figure 4B, element 21) into the

eyeball (see Figures 3-4 for illustration). Figure 4D shows the intraocular implant (21) comprises a tube (since it is cylindrical and has a hollow passage) having an inlet end (portion inside the eyeball), an outlet end (portion on surface of the eyeball), and a tube passage (36) extending between the inlet end and the outlet end for permitting aqueous humor to flow out of the eyeball (column 6, lines 41-45). Figure 4C shows a flange (25) connected to the tube (21) at the outlet end of the tube for placing on a surface of the eyeball.

Ritch et al. further disclose attaching the implant (21) to the delivery device (column 5, lines 60-63), cutting an opening in a portion of the conjunctiva of the eyeball (column 4, lines 49-50; since the conjunctiva covers eyeball, it is inherent that the incision must be made through the conjunctiva portion) that lies at a distance away from an intended implantation site (opposite from the implantation site; see Figure 3), placing the implant (21) by the delivery device (16) through the opening in the conjunctiva (column 4, lines 55-57), directing the implant (21) by the delivery device (16) to the implantation site (column 4, line 57), inserting the implant (21) through the sclera (18) at the implantation site (column 6, lines 6-31), and withdrawing the delivery device (column 6, lines 37-40).

Ritch et al. do not disclose a pointed tip at the inlet end of the tube (21). Like Ritch et al., Donowitz et al. disclose a tube (Figure 4, not labeled) for implanting into the eyeball. Unlike Ritch et al., Donowitz et al. disclose a pointed tip (36) at the inlet end (38) of the tube in order to facilitate easy insertion into the eye (column 3, lines 66-67, through column 4, lines 1-3). Regarding claim 35, Donowitz et al. further disclose

penetrating the sclera by the pointed tip (36) of the implant (column 4, lines 14-17), and inserting the implant through the sclera (column 4, lines 32-33). Therefore, to provide the implant of Ritch et al. with a pointed tip at the inlet end of the tube as taught by Donowitz et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate easy insertion into any portion of the eye desired, without the use of a separate piercing device.

11. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Donowitz et al., as applied to the claims above, and further in view of Rubinstein (Patent No. 5,433,701).

Ritch et al. in view of Donowitz et al. disclose a method as described above, however, Ritch et al. in view of Donowitz et al. do not disclose the beveled surface at the inlet end of the implant faces away from the iris. Like Ritch et al. in view of Donowitz et al., Rubinstein discloses an implant (Figures 2-3, element 10) for inserting into the eyeball. Unlike Ritch et al. in view of Donowitz et al., Rubinstein discloses the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), in order to minimize the possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). Therefore, to orient the implant of Ritch et al. in view of Donowitz et al. in such a way that the beveled surface at the inlet end of the implant faces away from the iris as taught by Rubinstein would have been obvious to one of ordinary skill in the art at the time the

invention was made in order to limit the possibility for obstruction of the implant passageway.

12. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Donowitz et al. as applied to the claims above, and further in view of Wong et al. (Patent No. 5,000,731).

Ritch et al. in view of Donowitz et al. disclose a method as described above, however, Ritch et al. in view of Donowitz et al. do not disclose a visible marker on the implant. Like Ritch et al. in view of Donowitz et al., Wong et al. disclose an implant (Figure 1, not labeled) providing a passage for fluid flow in order to reduce pressure within an organ. Unlike Ritch et al. in view of Donowitz et al., Wong et al. disclose circumferential holes (13) in order to facilitate fluid drainage (column 3, lines 43-47). Furthermore, it is obvious that these circumferential holes (13) may be used as "markers" since they are clearly visible on the implant. Therefore, to construct the implant of Ritch et al. in view of Donowitz et al. with markers, such as circumferential holes, as taught by Wong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate aqueous humor drainage.

13. Claims 39, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Wong et al.

Ritch et al. disclose a method of implanting an intraocular implant in an eyeball (column 3, lines 24-28) using a delivery device (Figure 4A, element 16) for implanting the intraocular implant (Figure 4B, element 21) into the eyeball (see Figures 3-4 for

illustration). Figure 4D shows the intraocular implant (21) comprises a tube (since it is cylindrical and has a hollow passage) having an inlet end (portion inside the eyeball), an outlet end (portion on surface of the eyeball), and a tube passage (36) extending between the inlet end and the outlet end for permitting aqueous humor to flow out of the eyeball (column 6, lines 41-45). Figure 4C shows a flange (25) connected to the tube (21) at the outlet end of the tube for placing on a surface of the eyeball.

Ritch et al. further disclose attaching the implant (21) to the delivery device (16) with the tip (35) of the rod-like instrument (28) penetrating the tube passage (36) of the implant (column 5, lines 60-63), cutting an opening in a portion of the conjunctiva of the eyeball (column 4, lines 49-50; since the conjunctiva covers eyeball, it is inherent that the incision must be made through the conjunctiva portion) that lies at a distance away from an intended implantation site (opposite from the implantation site; see Figure 3), placing the implant (21) by the delivery device (16) through the opening in the conjunctiva (column 4, lines 55-57), directing the implant (21) by the delivery device (16) to the implantation site (column 4, line 57), inserting the implant (21) through the sclera (18) at the implantation site (column 6, lines 6-31), and withdrawing the delivery device (column 6, lines 37-40).

Ritch et al. do not disclose the tube (21) has at least one side opening at the inlet. Wong et al. disclose an implant (Figure 1, not labeled) providing a passage for fluid flow in order to reduce pressure within an organ. Unlike Ritch et al., Wong et al. disclose side openings (13) in order to facilitate fluid drainage (column 3, lines 43-47). Furthermore, it is obvious that these side openings (13) may be used as "markers" since

they are clearly visible on the implant. Therefore, to construct the implant of Ritch et al. with side openings that may be used as markers as taught by Wong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate aqueous humor drainage.

14. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Wong et al. as applied to the claims above, and further in view of Donowitz et al.

Ritch et al. in view of Wong et al. disclose a method as described above, however, Ritch et al. in view of Wong et al. do not disclose a pointed tip at the inlet end of the tube (21). Like Ritch et al. in view of Wong et al., Donowitz et al. disclose a tube (Figure 4, not labeled) for implanting into the eyeball. Unlike Ritch et al. in view of Wong et al., Donowitz et al. disclose a pointed tip (36) at the inlet end (38) of the tube in order to facilitate easy insertion into the eye (column 3, lines 66-67, through column 4, lines 1-3). Donowitz et al. further disclose penetrating the sclera by the pointed tip (36) of the implant (column 4, lines 14-17), and inserting the implant through the sclera (column 4, lines 32-33). Therefore, to provide the implant of Ritch et al. in view of Wong et al. with a pointed tip at the inlet end of the tube as taught by Donowitz et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate easy insertion into any portion of the eye desired, without the use of a separate piercing device.

15. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Wong et al. as applied to the claims above, and further in view of Rubinstein.

Ritch et al. in view of Wong et al. disclose a method as described above, however, Ritch et al. in view of Wong et al. do not disclose a beveled surface at the inlet end of the implant that faces away from the iris. Like Ritch et al. in view of Wong et al., Rubinstein discloses an implant (Figures 2-3, element 10) for inserting into the eyeball. Unlike Ritch et al. in view of Wong et al., Rubinstein discloses a beveled surface (16) at the inlet end (24) of the implant (10) that faces away from the iris (Figure 2, element 21), in order to minimize the possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). Therefore, to construct and orient the implant of Ritch et al. in view of Wong et al. in such a way that a beveled surface at the inlet end of the implant faces away from the iris as taught by Rubinstein et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to limit the possibility for obstruction of the implant passageway.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
September 7, 2006

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9/4/06